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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,122	02/14/2002	Dale Clifford	6005.019	8896

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,122	CLIFFORD ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2004 and 28 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-14,16,23 and 25-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-14,16,23 and 25-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28, 2004 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 4, 6-14, 16, 23, and 25-38 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6-13, 16, 23, 25-35, and 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Veldhuizen et al. (USPN 6,656,178 B1, cited in previous office action). See figure 1e and respective portions of the specification. Referring to claims 1, 4, 25, and 27, Veldhuizen discloses an orthopedic implant configured to be implanted into a space between a first and second vertebra comprising a foraminous (col.2, lines 29-32), corrugated (waveform;

fig.1e) biocompatible material formed into a sleeve (1), which sleeve is configured as an endless loop (Veldhuizen has shown a sleeve 1 in fig.1e, and has disclosed the sleeve to form a full circle or full oval, col.3, lines 62-67; col.16, lines 28-31, a full circle/oval is devoid of ends, and thus being an endless loop. Although the sleeve may be an elongated strip prior to and during implantation, the end product is disclosed to form a full circle, thus an endless loop, and its prior configuration is irrelevant) the implant having a first end (2), second end (3), and a length dimension extending therebetween, the first and second ends being open (fig.1e), wherein the first open end (2) is adapted to contact a first vertebrae and the second open end (3) is adapted to contact the second vertebrae, the implant bearing a load between the first and second vertebrae (col.12, lines 34-38), wherein the biocompatible material has a thickness between about 0.5mm and 3.0mm (col.12, lines 19-21), and is titanium (the implant comprises titanium and alloys thereof, col.4, lines 5-10; col.12, lines 8-10), and wherein the implant has corrugations extending radially outward around an axis extending from the first to second end of the implant (see fig.1e).

Referring to claims 3, 6, 7, 26, 28, and 29, Veldhuizen discloses the implant to have a plurality of lobes and depressions (waves) having four and six (seen in fig.1e).

Referring to claims 8, 9, 11, 12, 30, 31, 33, and 34, Veldhuizen discloses the implant constructed of a foraminous (openings 6; col.12, lines 50-52) corrugated (waves) loop or sheet (fig.1e), having a substantially circular or elliptical shape (col.6, lines 3-5).

Referring to claims 10 and 32, Veldhuizen discloses an implant comprised of an intersecting network of landed regions (biocompatible material) that define a plurality of openings (6) in the network, wherein the openings (6) are dispersed among the landed regions (fig.3, 6; col.7, lines 1-4).

Referring to claims 13, 23, 35, and 38, Veldhuizen discloses an implant that surrounds bone graft material or bone growth promoting material (col.7, lines 52-53).

Referring to claims 16 and 37, Veldhuizen discloses the sleeve to be an inner sleeve, and having further an outer sleeve surrounding the inner sleeve (fig.10, 11c; col.7, lines 45-48).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 6-12, and 25-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (USPN 5,609,637, cited in previous office action) in view of Veldhuizen et al. (US 6,656,178, cited in previous office action). Referring to claims 1, 3, 6-7, 25-29, Biedermann discloses an orthopedic implant configured to be implanted into a space between a first and second vertebra (fig.4-6) comprising a foraminous (3), biocompatible material (col.2, lines 6-8) formed into a sleeve (wall 1), which sleeve is configured as an endless loop (fig.1), the implant having a first end (top), second end (bottom), a length dimension extending therebetween (fig.1-3), and a thickness (see figures), the first and second ends being open, wherein the first open end is adapted to contact a first vertebrae and the second open end is adapted to contact the second vertebrae (fig.4-6), and the implant bearing a load between the first and second vertebrae (fig.4-6). Biedermann does not disclose however, radially outwardly extending corrugations. Veldhuizen teaches in the same field of implants for the vertebrae, a

thin sheet implant (1; fig.1e) having radially outwardly extending corrugations (waves, plurality of lobes and depressions) in order to provide an implant with a thickness that provides flexibility, while adding surface area to provide increased support on the vertebra bones (col.11, lines 26-45; col.12, lines 19-21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Veldhuizen's teaching of having radial corrugations on thin sheet vertebra implants, with the sheet vertebra implant of Biedermann, in order to provide an implant with a thickness that provides flexibility, while adding surface area to provide increased support on the vertebra bones.

Referring to claim 4, Biedermann discloses the biocompatible material to be titanium (col.2, lines 6-7).

Referring to claims 8, 9, 11, 12, 30, 31, 33, and 34, Biedermann discloses the implant constructed of a foraminous (3) loop or sheet (1), having a substantially circular or elliptical shape (col.1, lines 26-29).

Referring to claims 10 and 32, Biedermann discloses an implant comprised of an intersecting network of landed regions (titanium sheet 1) that define a plurality of openings (3) in the network, wherein the openings (3) are dispersed among the landed regions (see figures).

Claims 1, 3-4, 6-11, 14, 16, 25-33, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schar et al. (USPN 6,176,881 B1, cited in previous office action). Referring to claims 1, 4, 25, and 27, Schar discloses an orthopedic implant configured to be implanted into a space between a first and second vertebra (col.1, lines 4-5) comprising a foraminous (30, fig.1), corrugated (5, fig.1, 7) biocompatible material formed into a sleeve (1),

which sleeve is formed of an endless loop (fig.1, 6, 7), and the corrugations extend radially outward around an axis extending from a first and second end of the implant, (the corrugations do in fact extend radially outward, each individual corrugation itself extends radially outward as a protrusion, and that one corrugations also extends around the implant axis, thus since a plurality of corrugations exist, a plurality of corrugations extend radially outward around the axis) the implant having a first end, second end, and a length dimension extending therebetween (fig.1, 7), the first and second ends being open, wherein the first open end is adapted to contact a first vertebrae and the second open end is adapted to contact the second vertebrae, and the implant bears a load between the first and second vertebrae (col.1, lines 4-5). Schar discloses the implant to be a load bearing biocompatible material and (rigid material, col.1, lines 34-35) having a thickness (fig.1, 6, 7), however is silent to mention any specific materials, or dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant out of titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. It also would have been an obvious matter of design choice to have a thickness of between about 0.5mm and 3.0mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Referring to claims 3, 6, 7, 26, 28, and 29, Schar discloses the implant to have a plurality of lobes and depressions (5, seen in fig.1, 3, 7) having four and six.

Referring to claims 8, 9, 11, 30, 31, and 33, Schar discloses the implant constructed of a foraminous (30) corrugated (5) loop or sheet (1), having a substantially circular shape (fig.6).

Referring to claims 10 and 32, Schar discloses an implant comprised of an intersecting network of landed regions (sleeve material, 1) that define a plurality of openings (30) in the network, wherein the openings (30) are dispersed among the landed regions (fig.1).

Referring to claims 16 and 37, Schar discloses the sleeve to be an inner sleeve (1), and having further an outer sleeve (2) surrounding the inner sleeve (fig.6).

Referring to claims 14 and 36, Schar discloses the sleeve (1) to have a plurality of openings (30, or openings seen in fig.6 where 25 and 26 protrude therethrough), the implant having a cerclage (24 +25+26) passing through the openings and secured to the sleeve (see fig.6).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER